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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,647	03/10/2000	Andrew D. Murdin	032931/0227	5021

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/523,647	MURDIN ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- Th MAILING DATE of this communication appears on th cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,11 and 39-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9,11 and 39-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/16/03.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Additionally Applicants amendment filed on October 16, 2003 has been received and entered. Claim 38 has been canceled and new claims 39-47 have been added, consequently claims 8-9, 11 and 39-47 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 8-9, and 11 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition comprising a vector which encodes SEQ ID NO: 2, does not reasonably provide enablement for a vaccine vector comprising at least 12 consecutive amino acids is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Additionally this rejection is applied to newly added claims 39-47.

Applicants are asserting that immunization *in vivo* using a DNA construct

expressing Seq ID NO: 2, i.e., pCACRMP60 (Figure 3) resulted in immune protection (Table 1 and Figure 4) as shown by subsequent inoculation to test the ability of the vaccine candidate to limit the growth of a sublethal C. pneumoniae challenge. Applicants further assert that the mouse model used in the instant application is an accepted disease model. Applicants further point out that protective immunity has been defined at page 50, lines 3-4 of the specification "as an accelerated clearance of pulmonary infection." Applicants finally assert that the vaccine vector has not merely induced an antigenic response, but was shown to accelerate clearance of pulmonary infection in an accepted disease model.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants assert that immunization in vivo using a DNA construct expressing SEQ ID NO: 2 resulted in immune protection as shown by subsequent inoculation to test the ability of the vaccine candidate to limit the growth of a sublethal C. pneumoniae challenge. However, Applicants are respectfully directed to the claims. The claims encompass DNA encoding SEQ ID NO: 2 as well as DNA encoding any 12 consecutive amino acids of SEQ ID NO: 2. Applicants have not shown which regions of SEQ ID NO: 2 are required to elicit their own definition of immunoprotection.

Fox (U.S. Patent Number 4,879,213) sets forth that "without knowing a protein's three dimensional structure there is no reliable method for determining which linear segments of the protein are accessible to the host's immune system" and that "whether the three dimensional structure is known or not, short linear polypeptides often appear not to have the ability to mimic the required secondary and tertiary conformational structures to constitute appropriate immunogenic and antigenic determinants." (See column 3) Consequently one of skill in the art

would be forced into excessive experimentation to identify which "fragments" are able to mimic the required secondary and tertiary structure of the full length polypeptide, and which fragments are capable of complexing with the antibodies or T cells that recognize the full length polypeptide.

Furthermore, Applicants claim language of "at least 12 consecutive amino acids from SEQ ID NO: 2, wherein the fragment defines an immunogenic epitope." is directly analogous to the situation addressed in In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). "A vaccine must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." Claims which recite "immunogenic epitopes" are claims which only require an antigenic response. This is simply not sufficient to enable the claim language of a "vaccine" as addressed in Wright.

Given the lack of working examples directed to any fragments, and the unpredictability of fragments successfully mimicking their full length proteins, one of skill in the art would be forced into excessive experimentation to practice the broadly claimed invention.

Accordingly this rejection is maintained for reasons of record, as well as those cited above.

2. The rejection of claims 8-9, and 11 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Additionally this rejection is applied to newly added claims 39-47. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants are asserting that the claims have been amended to delete reference to sequences having 75% identity, and that the claims have been amended to recite that "the fragment defines an immunogenic epitope of Chlamydia."

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants amendment to recite that "the fragment defines an immunogenic epitope of Chlamydia" are noted. However, Applicants still have not identified a "function" which identifies members of the genus. For instance, every protein sequence of 5 or greater amino acids can elicit an antibody under the proper conditions. Accordingly, Applicants "function" is shared by every member of the genus, and thus does not define the members of the genus.

Accordingly, this rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 102

3. The rejection of claims 8-9, and 11 under 35 U.S.C. 102(b) as being anticipated by Watson et al is withdrawn in view of Applicants amendment.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

4. Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 39 is directed to "another nucleic acid encoding an additional polypeptide which enhances the immune response to the polypeptide having SEQ ID NO: 2."

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition,

such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Accordingly, Applicants recitation of "enhances the immune response" does not sufficiently describe the description of the DNA molecule being claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 8-9, 11 and 39-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffais et al.

The claims are directed to a vaccine comprising a nucleic acid sequence which encodes SEQ ID NO: 2 or a fragment comprising at least 12 consecutive amino acids from SEQ ID NO: 2, wherein the fragment defines an immunogenic epitope of Chlamydia, and wherein the nucleic acid molecule is operably linked to a promoter functional in a mammalian cell.

Griffais et al (US Patent Number 6,559,294) disclose of nucleic acid sequences encoding the sequence of SEQ ID NO : 596, which is 100% identical to SEQ ID NO: 2

of the instant invention. Griffais et al further disclose of vectors, host cells, methods of producing the polypeptide and the viral promoter CMV. (See columns 17-40, 46 and claims).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Mark Navarro
Primary Examiner
November 18, 2003